Richard B. Belzer, Ph.D.
P.O. Box 319
Mt. Vernon, VA 22121
rbbelzer@post.harvard.edu
(703) 780-1850

October 26, 2007

The Honorable Susan E. Dudley
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

Dear Administrator Dudley:

On October 18, 2007, I met with Deputy Administrator Kevin Neyland, Desk Officer David Rostker, and representatives of the U.S. Patent and Trademark Office, concerning the Office's draft final regulation modifying information disclosure requirements related to patent applications (the "IDS Rule").[1] This meeting was conducted in accordance with procedures set forth in Section 6(b)(4)(A)-(B) of Executive Order 12,866. OMB has promptly posted a record of this meeting on its website, and included the written materials that I provided.[2]

Here is a short list covering the high points of my concern:

- USPTO determined that the proposed IDS Rule (published for public comment in July 2006) was "not significant" for purposes of Executive Order 12,866.[3]
- Despite its "not significant" designation, USTPO submitted the proposed rule for OMB review. However, the Office did not include an "assessment of the potential costs and benefits of the regulatory action," which it is required to have done for "significant" draft regulations pursuant to Section 6(a)(3)(B)(ii) of the Executive Order.
- I presented credible evidence showing that if USPTO's is right that the Rule does not impose any significant *economic* costs, then the incremental cost of the *paperwork burden alone* exceeds $7 billion per year, a figure at least 70 times

---

[1] RIN: 0651-AB95, "Changes to Information Disclosure Statement Requirements and Other Related Matters."

[2] See http://www.whitehouse.gov/omb/oira/0651/meetings/663.html.

[3] At the meeting, Mr. Robert Bahr, Senior Patent Counsel for the USPTO's Office of the Deputy Commissioner for Patent Examination Policy, stated that this was a typographical error but did not explain how the error occurred. USPTO has never issued a public correction.

greater than the threshold for economically significant regulatory actions set forth in Section 3(f)(1) of the Executive Order.[4]

- Whether its actual effects are economic or paperwork, the IDS rule is sure to be one of the largest economically significant regulatory actions of FY 2007.[5] Nevertheless, USPTO did not prepare a Regulatory Impact Analysis (RIA), nor has it disclosed any useful estimates of the rule's likely costs and benefits.
- USPTO asserts that the IDS Rule is exempt from the Administrative Procedure Act (APA) on the ground that it is merely a change in "the procedures to be followed in submitting information for consideration by the Office during the examination of an application for patent or reexamination of a patent" (71 Fed. Reg. 38818). Yet this mere change in procedure is one of general applicability and effect that happens to impose billions of dollars per year in costs on regulated parties.
- USPTO asserts that because the Rule is exempt from the APA, it also is exempt from the Regulatory Flexibility Act, and therefore the Office did not perform a Regulatory Flexibility Analysis.

With these facts as background, I want to bring to your attention a pair of new declarations that bear on the credibility of representations made by USPTO concerning the costs of USPTO's several interrelated rulemakings, of which the IDS Rule is one part. These declarations were submitted yesterday to the U.S. District Court for the Eastern District of Virginia, as part of an *amicus curiae* filing in two cases challenging the USPTO's recent "5/25 Rule".[6] For your convenience, I have attached copies of the amicus brief and the two declarations. All are public records.

---

[4] During this meeting I also formally raised concerns with a recent Information Collection Request submitted to OMB on September 26, 2007. See ICR Reference Number: 200707-0651-005. The declaration I provided to OMB on October 18, 2007, indicates that the paperwork burden for *just a few elements of the package* exceeds $7 billion per year. I asked OMB to treat my submission as a public comment on this ICR. At OMB's request, I agreed to postpone further discussion of these burden estimates until November, even though the formal 30-day public comment period expires today.

[5] In its March 2007 draft report to Congress on the benefits and costs of federal regulation, OMB says that the total cost of *all* major federal regulations issued in FY 2006 ranged from $3.7 to 4.2 billion. See http://www.whitehouse.gov/omb/inforeg/2007_cb/2007_draft_cb_report.pdf (Table 1-3).

[6] USPTO, "Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," 72 Fed. Reg. 46716ff. This final rule combines two draft final rules submitted to OMB: (1) RIN: 0651-AB93 ("Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing

It is not my purpose to opine on the merits of these cases or to speculate on their outcome. That cases such as these would be filed was predicted and communicated to OMB during its review of the precursors to the 5/25 Rule.[7] It was specifically noted that the administrative record was barren of useful, transparent, reproducible and unbiased information about costs and benefits; the Rule was likely illegally retroactive; and the USPTO lacked statutory authority to issue any Rule remotely like it. At that time, the Rule was estimated to impose paperwork burdens exceeding $1 billion.[8]

Nevertheless, OMB did not designate either rule as economically significant, did not designate either rule as major under the Congressional Review Act, and at least implicitly agreed with USPTO that neither rule was subject to the Regulatory Flexibility Act because small entities were not significantly affected.[9] Despite the fact that USPTO complied with none of the requirements of Executive Order 12,866 *except for submitting the drafts to OMB for review*, on July 9, 2007, both rules were coded as "consistent with change" with Executive Order 12,866.

The declarations provided to the Court in the *Tafas* and *SmithKline Beecham* cases support and reinforce the message contained in cost estimate I provided to OMB on October 18, 2007. One declaration is made by David J. Kappos, Vice President and Assistant General Counsel for Intellectual Property Law, International Business Machines Corp. (IBM). He estimates that it will cost IBM $10 million in "legal fees and

---

Patentably Indistinct Claims"); (2) RIN: 0651-AB94 ("Changes to Practice for the Examination of Claims in Patent Applications"). The combined package is now colloquially called the "5/25 Rule."

The two cases challenging the 5/25 Rule are *Tafas v. Jon W. Dudas, et al.* [1:07cv846 (JCC/TRJ)] and *SmithKline Beecham, et al. v. Jon W. Dudas, et al.* [1:07cv1008 (JCC/TRJ)].

[7] See Letter from David E. Boundy to Susan E. Dudley (June 15, 2007), Attachment E ("these rules are highly vulnerable to challenge under the Administrative Procedure Act"). Online at http://www.whitehouse.gov/omb/oira/0651/meetings/619-3.pdf.

[8] See Attachment M.

[9] The determination of no significant impact on small entities was made without the benefit of any documentation. The Office's certification of no significant impact (online at http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/ccfrcertificationanalysis.pdf) is dated June 29, 2007, but apparently it was not published until August 28, 2007 – seven days after the final rule was promulgated. It was never published for public comment. The declaration I provided OMB on October 18, 2007, is highly critical of the analysis contained in the USPTO certification ["I consider that report's quality as easily falling within the term 'junk science' (to the extent that the report qualifies for use of the term 'science' at all)"]; see ¶ 27, p. 4.

internal expenses" just to comply with the retroactivity provisions of the 5/25 Rule. This figure does not include the cost of preparing Examination Support Documents (the focus of the declaration I provided) nor does it include the value of intellectual property that the 5/25 Rule destroys (which the declaration I provided did not include at all).[10]

IBM is a large firm, to be sure, but it is still only one firm among thousands affected by the final 5/25 Rule and the draft final IDS Rule. It is inconceivable that the aggregate regulatory effects of the 5/25 Rule could be less than $100 million if the transactions cost alone, to IBM alone, is $10 million.

The declaration provided by Burt Magen, counsel to SanDisk, states that the retroactivity provisions of the 5/25 Rule will cost SanDisk $464,000 in additional fees it must pay to USPTO *under best-case conditions*. This estimate excludes paperwork burdens, which attend to the submissions that would accompany these fees (some of which Mr. Kappos included); and it also excludes the value of intellectual property that the 5/25 Rule destroys (which Mr. Kappos mentions but also excluded from his estimate). The destruction of intellectual property is a guaranteed result of both the final 5/25 Rule and the draft final IDS Rule simply because the best-case scenario described by Mr. Magen requires USPTO to implement these rules in a manner completely inconsistent with the Office's stated intent.[11]

Both these declarations, plus the one I provided to OMB, send a consistent message: these regulations have extraordinarily large impacts for which USPTO has not even begun to account. Indeed, these cost estimates are entirely consistent with public comments submitted to USPTO on both proposed rules, and to which (at least in the case of the final 5/25 Rule) the Office has been singularly unresponsive. The preamble to the draft final 5/25 Rule summarizes these comments and summarily rejects them, without providing any shred of analytic support.[12]

---

[10] USPTO asserts that the 5/25 Rule "will not effect a taking of private property or otherwise have taking implications under Executive Order 12630" (72 Fed. Reg. 46834). The basis for this claim is not disclosed.

[11] For example, Mr. Magen's cost figures assume that USPTO grants SanDisk the ability to comply with the final rule by dividing out claims into multiple applications (¶¶ 7-9). The amicus brief points out that USPTO has already told applicants that it will not do so (footnote 10 and accompanying text), and that the Office will be granting third and subsequent continuations only rarely (pp. 10-11). Thus, the destruction of intellectual property is assured.

[12] See 72 Fed. Reg. 46830-46834 (the Regulatory Flexibility Act does not require the preparation of a Regulatory Flexibility Analysis as long as the agency head certifies that the rule will not have a significant economic impact on a substantial number of small entities, irrespective of whether that certification has any analytic merit).

There is an obvious sense of urgency and anxiety about the draft final IDS Rule because today marks Day 92 of OMB's review, and I am unaware that Section 6(b)(2)(C) has been invoked. Yet there is overwhelming evidence that the IDS Rule would be immensely burdensome – more costly than all of the major federal rules promulgated in FY 2006 combined!

Therefore, I urge OMB to return the draft IDS Rule to USPTO "for further consideration of some or all of its provisions," as provided by Section 6(b)(3) of the Executive Order. USPTO has utterly failed to clearly and accurately communicate valid and reliable information to OMB and the public about the Rule's costs, benefits, and other effects. OMB lacks a publicly available analytical basis for making any other decision.

Sincerely,

Richard B. Belzer, Ph.D.

Attachments (3)

1. Brief for Amicus Curiae American Intellectual Property Law Association in Support of the "GSK" Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction
2. Declaration of David J. Kappos, on Behalf of IBM, in Support of AIPLA Amicus Brief in Matter of GSK Preliminary Injunction Motion to Stay New PTO Rules
3. Declaration of Burt Magen in Support of Amicus Curiae American Intellectual Property Law Association's Brief in Support of the GSK Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction